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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,588	07/24/2001	Michael S. Dobres	NOVA-0076	4361

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Woodcock Washburn Kurtz
MacKiewicz & Norris LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/911,588

Applicant(s)

DOBRES ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 February 2004 has been entered.

Status of the Claims

2. Applicant has amended claims 1, 9, and 20, and canceled claims 19. Claims 1-18, 20 and 28-34 are pending.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. A signed copy of Applicant's IDS submitted May 9, 2002 is included with this action.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 1-18, 20 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transforming a dicot

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plant with a transgene, comprising using leaf explants of Chrysanthemum (specification, p. 17-21), callus of petunia leaves (specification, p. 25), and callus of rosa petioles (specification, p. 28) using the methods taught in the specification, does not reasonably provide enablement for the broad scope of the claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The enablement issue are any explant and the specific conditions:

The nature of the invention and the breadth of the claims. Applicant's claims are drawn to a method of transforming a plant with a transgene, comprising (a) culturing an intact explant of the plant in nutritive medium, (b) electroporating the explant with a pulse length of at least about 50 milliseconds to produce a transformed explant; wherein the transgene is stably integrated into a chromosome of a cell of the transformed explant; to pulse lengths of 50-500 milliseconds, to two transgenes electroporated, and to a marker gene also electroporated, where the marker is on a second piece of DNA, to plants lacking a marker gene, to marker genes including IPT, to any dicot plant, also chrysanthemum, petunia and rose plants, to the NPT selectable marker, the CONSTANS gene, transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain.

The predictability of the art : Applicant claims all explants, including shoots, buds, flowers, leaves, petioles, stems, and roots, at all developmental stages and ages. Plant transformation procedures employing plant tissue culture are unpredictable.

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“Plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one.”, (Hansen et. al., 1999, Trends in plant Science, Vol 4, pages 226-231, see page 230). The regeneration of plants from explants is unpredictable, and explant selection is critical for successful plant regeneration. See Tisserat, in Plant Cell Culture, ed R.A. Dixon, 1985, IRL Press, Oxford, pages 79-105, especially page 80, Table 1, page 82, and Table 4, pages 85-90. Therefore it is unpredictable that transformation protocols and methods which work for Chrysanthemum leaf explants, callus of petunia immature leaves, and callus from rose petioles would function as desired for all explants and all dicot plants. The specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims.

The amount of guidance given, and the presence of working examples.

Applicant gives three working and one prophetic examples: Example 1, of electroporation of chrysanthemum leaf explants (specification, p. 17-21 with a gus gene and a NPT gene, producing gus-positive and kanamycin-resistant tissue. Example 2, a prophetic example of electroporation of chrysanthemum leaf explants with three independent genes—the GAI gene, the CONSTANS gene and a selectable marker. No transgenic tissue is produced in this example. Example 3, electroporation of petunia callus of immature petunia leaves (specification, p. 25), with a gus gene and a NPT

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gene, producing kanamycin-resistant tissue. Example 6, of electroporation of callus of rosa petioles (specification, p. 28) with IPT gene, producing tissue which is phenotypically similar to the expected transformed tissue, however without any biochemical or molecular characterization.

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Claim Rejections - 35 USC § 102

7. Claims 1-17, 20, 28 and 30-33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dev et al, US 5,859,327 issued January 12, 1999, as recited again in part below:

Dev teaches a method for transforming a plant (Abstract, and col 10, lines 23-27) with a transgene, comprising the steps of culturing an intact explant (col 12, line 29) in nutritive medium (col 15, lines 60-66), electroporating the explant with a pulse length of about 50 milliseconds (col 8, lines 58-61 and 65) , to produce a transformed explant, where in the transgene is stably integrated (Abstract, and col 10, lines 23-27). Dev also teaches a pulse length of 90-250 milliseconds (col 16, lines 40-55), 90-200 ms, and 90-150 (col 16, lines 40-55), and a petunia explant (col 14, lines 66-67). Dev also teaches transformation with at least one structural gene (claim 6, for example) and transformation with a marker gene (claim 10, for example).

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Furthermore, Dev teaches (column 12, lines 24-28) embryos being maintained in MS media prior to electroporation, and cotyledons explants grown in Hoagland's medium prior to electroporation (column 15, lines 57-59).

Applicant traverses, stating primarily that Dev describes placing immature embryos in an electroporation buffer containing KCl, CaCl₂, Hepes, and mannitol, and then placing on ice for 3 hours. Applicant asserts that the electroporation buffer described by Dev is not a nutritive medium because it lacks essential components of nutritive medium.

Applicant's traversal has been considered and is unpersuasive because Dev teaches (column 12, lines 29-34) embryos placed with medium containing KCl, CaCl₂, Hepes buffer and mannitol pH 7.2, which is a nutritive medium containing salts and a carbon source.

Applicant traverses, stating primarily that (response, page 10) zero degrees is not a temperature that is conducive the plants growth, and hence is not a temperature at which a nutritive medium is required.

Applicant's traversal is unpersuasive. Applicant is arguing limitations that are not in the claims. No claims are drawn to specific temperatures.

Accordingly, Dev anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. Claims 1-18, 20 and 28-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dev as discussed above, and further in view of Applicants admitted prior art. Claims 1-17, 19, 20, 28 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dev discussed supra. This rejection is recited below:

The teachings of Dev are discussed above. Dev does not teach an IPT gene, the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain.

Applicants admitted prior art (p22) teaches the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain. IPT genes for transformation were known as taught at the paragraph bridging pages 14-15.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the NPT gene of Dev with the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, or transgenes comprising a signal transduction domain, or the IPT gene, of

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Applicant's admitted prior art, for the purpose of , enhancing and controlling the flowering and stalk height characteristics of the ornamental plants taught by Dev. And the number of transgenes or the particular selectable marker would have been a matter of choice. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Applicant traverses, stating primarily that they traverse the rejection because it appears to be based on the assumption that the Dev patent teaches all the limitations of the claims except those noted.

Applicant's traversal has been considered and is unpersuasive because the rejection over Dev under 102 (b) is maintained as recited supra, and the additional limitations would have been obvious as previously stated.

Remarks

9. No claim is allowed


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

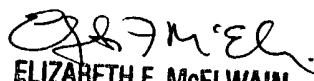
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Group 1638
April 16, 2004




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800